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**Statement complementing the scientific opinion on application
EFSA-GMO-NL-2010-78 to cover the safety of soybean MON 87705 oil for
commercial frying**

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Abstract: In this statement, the EFSA GMO Panel responds to a request from the European Commission (EC) to assess the safety of soybean MON 87705 oil for commercial frying. The applicant provided exposure assessments based on total and partial substitutions of conventional soybean, rapeseed and sunflower oils with the soybean MON 87705 oil in foods (salad dressings, margarines and spreads, mayonnaise, crackers and salty snacks and soybean/rapeseed/sunflower oils processed foods). No distinction was made between commercial and domestic use, nor whether the oils were used in frying or not. The EFSA GMO Panel considers that this exposure scenario is the most pertinent in that it addresses not only the question raised by the EC about the possible use of soybean MON 87705 oil in frying, but also other possible food uses. Having assessed total replacement, the most conservative scenario arising from both domestic and commercial use of the oil, the EFSA GMO Panel concluded that the use of soybean MON 80775 oil does not impact on human health and nutrition. The Panel recommends a post-market monitoring plan for the marketed foods and feed.

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SCIENTIFIC OPINION

Statement complementing the scientific opinion on application EFSA-GMO-NL-2010-78 to cover the safety of soybean MON 87705 oil for commercial frying¹

EFSA Panel on Genetically Modified Organisms (GMO)^{2, 3}

European Food Safety Authority (EFSA), Parma, Italy

ABSTRACT

In this statement, the EFSA GMO Panel responds to a request from the European Commission (EC) to assess the safety of soybean MON 87705 oil for commercial frying. The applicant provided exposure assessments based on total and partial substitutions of conventional soybean, rapeseed and sunflower oils with the soybean MON 87705 oil in foods (salad dressings, margarines and spreads, mayonnaise, crackers and salty snacks and soybean/rapeseed/sunflower oils processed foods). No distinction was made between commercial and domestic use, nor whether the oils were used in frying or not. The EFSA GMO Panel considers that this exposure scenario is the most pertinent in that it addresses not only the question raised by the EC about the possible use of soybean MON 87705 oil in frying, but also other possible food uses. Having assessed total replacement, the most conservative scenario arising from both domestic and commercial use of the oil, the EFSA GMO Panel concluded that the use of soybean MON 87705 oil does not impact on human health and nutrition. The Panel recommends a post-market monitoring plan for the marketed foods and feed.

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KEY WORDS

GMO, soybean oil, MON 87705, exposure assessment, dietary intake, nutrition

¹ On request from the European Commission, Question No EFSA-Q-2013-00423, adopted on 4 December 2013.

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³ Acknowledgement: The Panel wishes to thank the members of the Working Group on Food and Feed for the preparatory work on this scientific opinion, in particular Hildegard Przyrembel and Peter Aggett and EFSA staff member Yi Liu, for the support provided to this scientific opinion.

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SUMMARY

The European Commission requested the EFSA GMO Panel, on 7 January 2013, to complement its opinion related to soybean MON 87705 by an assessment of the safety of using soybean MON 87705 oil for commercial frying. To do so, EFSA requested data from the applicant. The applicant provided an exposure assessment based on three substitution levels to replace conventional soybean, rapeseed and sunflower oils in foods categorised in the UK National Diet and Nutrition Survey of 2008–2010. Foods considered are salad dressings, margarines and spreads, mayonnaise, crackers and salty snacks and soybean/rapeseed/sunflower oils processed foods. No distinction was made between commercial and domestic use, nor whether the oils were used in frying or not. The average and upper percentile intakes (expressed as g/day and as E % of the total diet) of five fatty acids (palmitic, stearic, oleic, linoleic and α -linolenic acid) arising from a total substitution of other oils by soybean MON 87705 oil were estimated, and the likely changes in total fatty acid consumption from the whole diet were calculated.

The EFSA GMO Panel considers that this exposure scenario is the most pertinent in that it addresses not only the question raised by the EC about the possible use of soybean MON 87705 oil in frying, but also other possible food uses. The total replacement constitutes the most conservative scenario arising from both commercial and non-commercial uses of the oil. The EFSA GMO Panel concluded that the use of soybean MON 80775 oil does not impact on human health and nutrition. The Panel recommends a post-market monitoring plan, focusing on the collection of consumption data for the European population, for the marketed foods and feed.

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BACKGROUND

Genetically modified soybean MON 87705 has an increased oleic acid content and exhibits tolerance to glyphosate-containing herbicides. The intended uses for soybean MON 87705 oil, as proposed by the applicant, are in margarine, salad dressing, mayonnaise and home-use liquid vegetable oil, excluding the use for commercial frying.⁴ On 30 October 2012 the EFSA GMO Panel published a Scientific Opinion on application EFSA-GMO-NL-2010-78 for the placing on the market of the soybean MON 87705 for food and feed uses, import and processing under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2012).

During the authorisation process, the EC noted that while the application is of full scope (for all food and feed uses, import and processing), the scientific opinion does not conclude on the safety of the oil for commercial frying. On 7 January 2013 the European Commission asked the EFSA GMO Panel to complement its opinion on soybean MON 87705 oil to include an assessment of the safety of the oil for commercial frying, and to request missing data from the applicant, if needed.

On 3 April 2013 EFSA requested the applicant to provide an exposure assessment on EU consumers for the oil extracted from soybean MON 87705 when used for commercial frying and to include scenarios for mean and high consumers. On 22 May 2013 EFSA received the requested data.

The EFSA GMO Panel evaluated these data, and expresses its view in this statement. According to Regulation (EC) No 1829/2003, this statement complements the scientific opinion, which is the report requested under Articles 6(6) and 18(6) of that Regulation, and will be part of the EFSA overall Opinion in accordance with Articles 6(5) and 18(5).

TERMS OF REFERENCE

The EFSA GMO Panel was requested, in accordance with Articles 6(6) and 18(6) of Regulation (EC) No 1829/2003, to complement its scientific opinion on soybean MON 87705 on the safety of oil for commercial frying.

⁴ Quoted from Application EFSA-GMO-NL-2010-78/applicant response to EFSA questions of 11 November 2011 (received by EFSA on 29 December 2011) as “It needs to be repeated that MON 87705 soybean oil, similar to commodity soybean oil, has a polyunsaturated fatty acid (PUFA) content that is not optimal for commercial frying (i.e., high temperature and repeated frying); hence, MON 87705 soybean oil is not targeted for these applications.”

EVALUATION

1. Introduction

This request from the European Commission concerns a published scientific opinion for application EFSA-GMO-NL-2010-78 on soybean MON 87705 for food and feed uses, import and processing (EFSA GMO Panel, 2012). The GMO Panel stated in its scientific opinion that “The applicant did not provide data which would allow a nutritional assessment of soybean MON 87705 oil when used for commercial frying.” Commercial and domestic frying is not an application intended by the applicant for soybean MON 87705 oil. In the light of this request from the EC, EFSA asked the applicant for an exposure assessment based on the use of soybean MON 87705 oil for commercial frying. In this statement, the EFSA GMO Panel evaluates the additional data provided by the applicant.

2. Exposure assessment addressing the soybean MON 87705 oil in all food uses including frying⁵

2.1. Exposure scenarios

Soybean, rapeseed and sunflower oils account for 80 % of vegetable oil consumed in the UK (FAOSTAT, 2012). In this assessment soybean MON 87705 oil is assumed to replace conventional soybean, rapeseed and sunflower oils in foods consumed by the UK population aged 19 years or older. Consumption data are taken from the UK National Diet and Nutrition Survey of 2008–2010 (Bates et al., 2011). These consumption data are more recent than those used in the initial submission and assessment of soybean MON 87705 oil (EFSA GMO Panel, 2012). Foods considered are: salad dressings, margarines and spreads, mayonnaise, crackers and salty snacks and soybean/rapeseed/sunflower oils processed foods. The content of soybean/rapeseed/sunflower oils in foods belonging to these categories of foods are calculated from available databanks (FSA, 2002). The Panel considers that this scenario is the most pertinent in that it addresses not only the question raised by the EC about the possible use of soybean MON 87705 oil in frying, but also other possible food uses. The EFSA GMO Panel considers this selection of food items conservative, because it covers the majority of foods made of or with vegetable oils, including both the commercial and the domestic use of oils, also for frying.

The applicant provided an assessment based on three substitution levels of three vegetable oils with soybean MON 87705 oil. The EFSA GMO Panel selected the 100 % substitution as the most conservative scenario arising from both domestic and commercial use of the vegetable oils. The average and upper percentile intakes (expressed as g/day and as E % of the total diet) of fatty acid groups (SFAs [saturated fatty acids], MUFAs [monounsaturated fatty acids], n-3 PUFAs [polyunsaturated acids] and n-6 PUFAs) are calculated (see Table 1).

Table 1: Estimated daily intake (E %) of fatty acid groups before and after the replacement. Predicted changes in the total diet with respect to fatty acid groups (SFAs, MUFAs, PUFAs) are given as percentage of total energy in adults > 19 years old (average per capita and 97.5th percentile consumers) through replacement of all consumed vegetable oils (soybean, rapeseed, sunflower) by soybean MON 87705 oil

| Fatty acid group | Males | | | | Females | | | |
|------------------|------------------------|-------|-------------------------|-------|------------------------|-------|-------------------------|-------|
| | Average ^(a) | | 97.5th % ^(b) | | Average ^(a) | | 97.5th % ^(b) | |
| | Before | After | Before | After | Before | After | Before | After |
| SFA | 12.4 | 9.9 | 19.7 | 15.2 | 12.5 | 10.0 | 19.4 | 15.3 |
| MUFA | 11.9 | 18.3 | 17.3 | 26.6 | 11.6 | 17.6 | 17.0 | 25.9 |
| n-3 PUFA | 0.9 | 0.9 | 2.2 | 2.1 | 1.0 | 0.9 | 2.1 | 2.0 |
| n-6 PUFA | 4.8 | 2.8 | 8.1 | 4.7 | 4.9 | 2.9 | 8.8 | 5.2 |

(a): See Table 8-A-1 in the Additional information received in June 2013

(b): See Table 8-B-1 in the Additional information received in June 2013

⁵ Information received on 22 May 2013

The applicant estimated the average total fat consumption of the UK population aged 19 years or older: males 80.2 g/day; females 60.8 g/day. Soybean, rapeseed and sunflower oil contribute 40 g fat/day (19.4 E %) to the total fat intake per person per day; males 46 g/day (19.4 E %); females 34.4 g fat/day (19.3 E %). That means that theoretically 57.4 % and 56.6 % of total dietary fat can be replaced by soybean MON 87705 oil in males and females, respectively, and the likely changes in total fatty acid consumption from the whole diet are calculated. The average intakes of five fatty acids (palmitic C16:0, stearic C18:0, oleic C18:1, linoleic C18:2 and α -linolenic acid C18:3) are also estimated, and the percentage changes calculated (see Table 2). Based on this consideration, the effects that a 100 % substitution of all conventional soybean, rapeseed and sunflower oils by soybean MON 87705 oil would have on the daily fatty acid intake in the total diet are predicted (see Table 2).

Table 2: Percentage of changes in fatty acid intake under the 100% substitution scenario

| Fatty acids (FA) | Males | | | Females | | |
|--------------------------------|--------------------------------------|-------------------------------------------|-----------------------------------------------|--------------------------------------|-------------------------------------------|-----------------------------------------------|
| | % Change in FA intake ^(a) | % Replaceable vegetable oil in total diet | Predicted % change of FA intake in total diet | % Change in FA intake ^(a) | % Replaceable vegetable oil in total diet | Predicted % change of FA intake in total diet |
| Palmitic acid C16:0 | −60.0 | 57.4 | −34.4 | −60.0 | 56.6 | −34.4 |
| Stearic acid C18:0 | 25.0 | 57.4 | 14.3 | 25.0 | 56.6 | 14.3 |
| Oleic acid C18:1 | 93.5 | 57.4 | 53.7 | 91.9 | 56.6 | 52 |
| Linoleic acid C18:2 | −72.4 | 57.4 | −41.6 | −72.4 | 56.6 | −41 |
| α -linolenic acid C18:3 | 0 | 57.4 | 0 | −9.1 | 56.6 | −5.2 |

(a): % Change in FA intake = (intake after substitution – intake before the substitution)/intake before the substitution; see Table 7-A-1 in the Additional information received in June 2013

Predicted % change = % change of FA intake \times % of replaceable vegetable oil in total diet

2.2. Assessment

EFSA has not set a dietary reference value (DRV) for SFAs. Several international and national authorities on nutrition recommend SFA intakes < 10 E % (EFSA NDA Panel, 2010). The baseline SFA intake in UK adults (see Table 1) is higher than 10 E %, and decreases after substitution with soybean MON 87705 oil to become nearer to the recommended level, which can be considered desirable.

As expected, the intake of oleic acid, and consequently that of MUFA, considerably increases when vegetable oils are replaced with soybean MON 87705 oil. No dietary reference value has been set for MUFAs by EFSA (EFSA NDA Panel, 2010). However, the calculated increased intakes of MUFAs (18 E % vs. 12 E %) are in the range of those observed for adults in EU countries (11–21 E %). Such an increase is not expected to have an adverse impact on health.

Alpha-linolenic acid (ALA) is the main dietary *cis*-n-3 PUFA. EFSA has proposed an adequate intake (AI) for ALA of 0.5 E % (EFSA NDA Panel, 2010). The n-3 PUFA intake, around 1 E % at baseline in men and women, would fall by about 5 % in the substitution scenario (see Table 1). The EFSA GMO Panel is of the opinion that such a decrease in the intake of n-3 PUFA is of no concern for human nutrition.

Linoleic acid is the main dietary *cis*-n-6 PUFA. EFSA has proposed an AI for linoleic acid of 4 E % (EFSA NDA Panel, 2010). As Table 1 shows, the average and 97.5th percentile intakes of n-6 PUFA

for adults would fall by around 40 % from > 4 %E to < 4 %E. The EFSA GMO Panel considers that this is unlikely to be of concern, because linoleic acid deficiency has not been observed at intakes > 1E % (EFSA NDA Panel, 2010) and because the 100 % replacement by soybean MON 87705 oil of vegetable oils in the diet is unlikely to occur.

CONCLUSIONS AND RECOMMENDATIONS

CONCLUSIONS

The EFSA GMO Panel considers that this assessment covers all food uses for soybean MON 80775 oil, and that it does not impact on human health and nutrition.

The Panel notes that the suitability of oil for frying purposes depends on the behaviour of that oil when exposed continuously or repeatedly to high temperatures with regard to hydrolysis, oxidation, degradation and polymerisation. As a rule, oils containing more than 2 or 3 % of alpha-linolenic acid are regarded as not suitable for frying because it negatively influences the stability of the oil and the flavour quality of fried foods.

RECOMMENDATIONS

Data considered in this statement fills the data gap identified in the previous assessment (EFSA GMO Panel, 2012). Being in possession of the complete data for dietary exposure, the EFSA GMO Panel is now in position to make a recommendation on the post-market monitoring plan.

A proposal for a post-market monitoring plan needs to be provided by the applicant (EFSA GMO Panel, 2011). EFSA recommends that the post-market monitoring plan focus on the collection of consumption data for the European population.

For specific labelling, the applicant proposed that, for example, operators handling products containing or consisting of oil produced from soybean MON 87705 shall be required to label these products with the words “increased oleic acid oil produced from genetically modified soybean”.

DOCUMENTATION PROVIDED TO EFSA

1. Request from EC to EFSA, received on 7 January 2013, to complement the scientific opinion on soybean MON 87705 for commercial frying.
2. Acknowledgement letter from EFSA to EC, dated 4 April 2013.
3. Letter from EFSA to Monsanto, sent on 3 April 2013, requesting data.
4. Reply from Monsanto to EFSA, received on 22 May, submitting data.

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ABBREVIATIONS

| | |
|------|----------------------------|
| E % | % Energy |
| MUFA | Monounsaturated fatty acid |
| n-3 | Omega 3 |
| n-6 | Omega 6 |
| PUFA | Polyunsaturated fatty acid |
| SFA | Saturated fatty acid |